IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HQ SPECIALTY PHARMA CORP. and WG CRITICAL CARE, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 21-1714 (MN)
FRESENIUS KABI USA, L.L.C.,	)	
Defendant.	)	

MEMORANDUM OPINION

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March 31, 2025
Wilmington, Delaware

NOREIKA, U.S. DISTRICT JUDGE:

From August 26 to 30, 2024, the Court presided over a five-day jury trial in this patent case between Plaintiffs HQ Specialty Pharma Corporation ("HQ") and WC Critical Care, LLC ("WGCC") (together, "Plaintiffs"), and Defendant Fresenius Kabi USA, LLC ("Fresenius" or "Defendant"). (*See* D.I. 285, 286, 287, 288, 289 (together, ("Jury Tr.")). On August 27 and 28, after the jury left for the day, the Court held a bench trial on Defendant's claim that Plaintiffs engaged in inequitable conduct during prosecution of the patent-in-suit, thereby rendering it unenforceable. (D.I. 290, 291 ("Bench Tr.")). The parties completed post-trial briefing on October 23, 2024, including the submission of proposed findings of fact. (D.I. 283, 284, 297, 298, 301).

For the reasons that follow, the Court finds that Defendant has failed to prove inequitable conduct by clear and convincing evidence.

I. BACKGROUND

This case concerns U.S. Patent No. 10,130,646, entitled, "Calcium Gluconate Solutions in Flexible Containers" ("the '646 patent"). (*See* JTX-1 at 2). The '646 patent claims a terminally sterilized calcium gluconate solution packaged in a free-flex plastic bag. (*Id.*). In other words, it claims a ready-to-use bag that allows hospitals to administer intravenous ("IV") calcium gluconate treatment to patients. The '646 patent is owned by HQ and names Joseph Pizza as the sole inventor. (*Id.*).

Plaintiffs filed this action on December 3, 2021, alleging that Fresenius makes a calcium gluconate bag product ("the Accused Product") that infringes claims 1, 2, and 3 of the '646 patent (collectively, "the Asserted Claims"). (*See id*. at 5-6). Fresenius counterclaimed for invalidity and unenforceability (D.I. 26) though it later stipulated to infringement (D.I. 90 at 2-3). From

August 26 to 30, 2024, the Court presided over a jury trial. (*See* Tr.). At that trial, Plaintiffs sought to prove damages for infringement, while Fresenius endeavored to invalidate the Asserted Claims for obviousness and improper inventorship. At the conclusion of trial, the jury found that Fresenius had not proven by clear and convincing evidence that the invention of the '646 patent was obvious but had proven that claims 2 and 3 are invalid for lack of proper inventorship.[1] (D.I. 260 at 2-3). On September 16, 2024, the Court entered judgment on the jury verdict under Rule 58(b) of the Federal Rules of Civil Procedure. (D.I. 277).

On September 30, 2024, Fresenius filed its opening post-trial brief and proposed findings of fact on inequitable conduct. (D.I. 283, 284). Plaintiffs responded on October 15, 2024, and Fresenius replied on October 22, 2024.[2] (D.I. 297, 298, 301).

II. FINDINGS OF FACT ("FF")

A. The Parties & Relevant Non-Parties

1. Plaintiff HQ Specialty Pharma is a New Jersey corporation headquartered at 120 Route 17 North, Suite 130, Paramus, New Jersey 07652. (D.I. 215, Ex. 1 ¶ 1). HQ develops medical products and works to get them approved by the Food and Drug Administration. (Jury Tr. at 183:1-5).

2. Plaintiff WG Critical Care is a New Jersey limited liability company, also having a principal place of business at 120 Route 17 North, Paramus, New Jersey 07652. (D.I. 215, Ex. 1

[1] The jury also found that claim 1 was not invalid for improper inventorship. (D.I. 260 at 1).

[2] The parties have also briefed motions to correct inventorship and for judgment as a matter of law. (D.I. 267, 293, 295). The Court's decision on those motions will be issued in due course.

¶ 2). WGCC is an affiliate of HQ and commercializes HQ's products. (Jury Tr. at 182:17-183:14). Among other things, WGCC sells IV bags and injectable products. (*Id.* at 182:18-19).

3. Defendant Fresenius Kabi USA is a Delaware limited liability company, with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. (D.I. 215, Ex. 1 ¶ 4).

4. Non-party PharmaSphere, LLC ("PharmaSphere") is a New Jersey-based pharmaceutical company and the parent of affiliates HQ and WGCC. (*Id.* ¶¶ 1-3; Jury Tr. at 183:1-14; 264:23-265:9).

5. Non-party InfoRLife SA ("InfoRLife") is a Swiss medical research and development laboratory located in Campascio, Switzerland. (DTX-276). HQ hired InfoRLife as a contractor to assist in the research and development of the calcium gluconate product that is the subject of the '646 patent. (*Id.*; Jury Tr. at 277:5-278:24).

B. <u>Trial Witnesses & Relevant Non-Witnesses</u>

6. Joseph Pizza is the founder, CEO, and President of Plaintiffs' parent company, PharmaSphere. (Jury Tr. at 264:23-25). He is the sole named inventor of the '646 patent. (JTX-1 at 2). Mr. Pizza testified live at trial and the Court was able to evaluate his credibility.

7. Jeanne Squeglia is an employee of HQ and VP of Technical Affairs. (Jury Tr. at 765:6-14). In that role, she works to get Plaintiffs' products developed, manufactured by third-party lab contractors, and approved by the FDA. (*Id.*). She assisted in coordinating the prosecution of the '646 patent on behalf of HQ and Mr. Pizza. (Bench Tr. at 23:7-15). Ms. Squeglia testified live at trial and the Court was able to evaluate her credibility.

8. Richard Kelly, a partner at the law firm Oblon, McClelland, Maier & Neustadt, LLP, prosecuted the '646 patent on behalf of HQ and Mr. Pizza. (*Id.* at 12:24-13:3; Jury Tr. at

576:9-12; JTX-1 at 2). Mr. Kelly testified by video deposition and the Court was able to evaluate his credibility.

9. Dr. Sergio Dusci is, and was at all relevant times, an employee of InfoRLife. (*See* Jury Tr. at 278:10-14). He oversaw InfoRLife's work on Plaintiffs' calcium gluconate product. (*Id*. at 317:15-318:17, 585:6-8). Dr. Dusci holds a PhD in chemistry and has more than 20 years' experience working with pharmaceutical formulations. (*Id*. at 313:17-314:7). Dr. Dusci was not called to testify at trial and was not deposed during pretrial litigation. Accordingly, Dr. Dusci provided no testimony, and the Court was not able to evaluate his credibility.

C. Calcium Gluconate

10. Calcium gluconate is a medical compound "used for treating individuals having low levels of calcium ions in their blood system." (JTX-1 at 1:21-22). The drug is nearly 100 years old, "dating back to at least the 1930s." (*Id*. at 1:32-34). For most of that time, it was primarily available as supersaturated solutions "in 10 mL glass vials and 100 mL rigid plastic bottles." (*Id.*).

11. Hospitals compound calcium gluconate bags for intravenous administration. (*Id.* at 1:53-65). Often, hospitals directly transfer the calcium gluconate from the vial or container into plastic bags, which are then used for IV administration. (*Id.*). Hospitals prepare such bags in advance by adding the calcium gluconate solution to an IV solution, a process called dilution. (*Id.*). In addition to being made by hospitals, these pre-prepared bags may be made a pharmacy. (*Id.*).

12. Typical pre-prepared calcium gluconate bags have a shelf life at room temperature of approximately 45 to 70 days. (*Id.* at 1:59-61). When stored in a vial – rather than a bag – calcium gluconate has a shelf life of about three years. (*Id*. at 1:66-2:3).

13. From 1999 to 2008, APP Pharmaceuticals, Inc. ("APP") sold calcium gluconate injection products in vials. (D.I. 215, Ex. 1 ¶ 56). In 2008, APP was acquired by an affiliate of Fresenius. (*Id.* ¶ 55). It continued to sell calcium gluconate vials following the acquisition. (*Id.* ¶ 56). APP later became known as Fresenius. (*Id.* ¶ 55).

14. In 2017, the FDA approved Fresenius' calcium gluconate injectable vial products. (*Id.* ¶ 56). Until that time, APP and Fresenius (as well as other companies) had been allowed to sell calcium gluconate vials without FDA approval, because calcium gluconate products were already in existence at the time of the amendment to the Federal Food, Drug, and Cosmetic Act in 1962, which required all drugs in the U.S. to be approved as safe and effective. (*Id.* ¶ 57).

15. According to the label for Fresenius' FDA-approved calcium gluconate vials ("the 2017 FK Label"), calcium gluconate IV products were sold without FDA approval in the U.S. starting in 1941. (*Id.* ¶ 58). Such products are sometimes referred to as "grandfathered products." (*Id.* ¶ 59).

16. The products covered by the 2017 FK Label had the same formulation as the product that Fresenius (and APP before it) sold as an unapproved, grandfathered product prior to 2016. (*Id.* ¶ 60; Bench Tr. at 86:3-13).

D. <u>The '646 Patent</u>

17. The '646 patent, entitled "Calcium Gluconate Solutions in Flexible Containers," issued on November 20, 2018. (JTX-1 at 2).

18. Mr. Pizza is the sole named inventor of the '646 patent. (*Id.*). HQ is the owner and assignee of the patent. (*Id.*). At times, they are referred to together herein as "Applicants."

19. The '646 patent has three claims. (*Id.* at 6:12-7:6).

20. The first claim claims: "A terminally sterilized aqueous calcium gluconate solution comprising: sodium chloride; and 1 to 15 wt. % calcium gluconate and from 1 to 19 wt. parts of calcium saccharate per 100 wt. parts of calcium gluconate packaged in a flexible plastic container with the remainder water, wherein the flexible plastic container is a bag, and the solution has a pH of from 6 to 8.2." (*Id.*, Cl. 1).

21. The second claim, which depends from claim 1, claims: "The terminally sterilized aqueous calcium gluconate solution of claim 1, wherein the solution comprises 19.6 mg/ml of calcium gluconate monohydrate, about 0.9 mg/ml of calcium D-saccharate, and about 6.75 mg/ml sodium chloride." (*Id.*, Cl. 2).

22. The third claim, which depends from claim 2, claims: "The terminally sterilized aqueous calcium gluconate solution of claim 2, wherein the solution has a shelf [life] of at least about 24 months when stored at 25° C." (*Id.*, Cl. 3).

23. The '646 patent issued from the '705 application, which was filed on January 11, 2018. (*Id.* at 2; DTX-1.001).

24. The '646 patent is a continuation of the '184 application, which was filed on July 25, 2017, and abandoned during prosecution. (JTX-1 at 2; Bench Tr. at 3:6-8).

25. In "References Cited," the '646 patent lists U.S. Patent Nos. 1,965,535 ("Pasternak") and 8,829,054 ("Owoo"), as well as an article on tonicity ("Allen" or "Lloyd"). (JTX-1 at 2).

26. The '646 patent application was originally filed with 7 claims. (DTX-1.014).

27. There were no pH limitations in original claims 1-4 of the '646 patent application; original claim 5 recited that "the solution has a pH of from 6 to 8.2." (*Id.*; Bench Tr. at 38:13-39:6).

28. In an Office Action dated March 2, 2018, patent examiner Kevin E. Weddington ("the Examiner") initially rejected claims 1, 2, 3, 4, 6, and 7 as obvious over Pasternack in view of Owoo and further in view of Allen. (DTX-1.056-057; Bench Tr. at 39:7-25).

29. In response, Applicants amended claim 1 to include the limitations of dependent claims 2, 3, 4, and 5. (DTX-1.142-45). This included the dependent element of claim 5, "wherein the solution has a pH of from 6 to 8.2." (*Id.*; Bench Tr. at 40:10-41:8). Nonetheless, the pH range of 6.0 to 8.2 is not explicitly cited in the Examiner's rejection, Applicants' arguments, or the Examiner's Notice of Allowance. (*See* DTX-1.151-57).

30. On July 23, 2018, following the amendments, the Examiner allowed the claims of the '646 Patent. (*Id.*; Bench Tr. at 41:5-8). The Examiner noted that the "amendments to claim 1 recite limitations not disclosed in the combinations of the prior art." (DTX-1.157).

31. U.S. Patent No. 10,342,813 ("the '813 patent") was a continuation patent that was prosecuted and issued after the '646 patent issued. The application for the '813 patent was filed on November 13, 2018, with original claims 1-3 that did not recite any pH limitations. (DTX-3.001, 3.022).

32. The same Examiner rejected the original claims of the '813 patent application for obviousness over Pasternack, Owoo, and Lloyd. (DTX-3.040-46).

33. The Applicants overcame the objection and obtained a Notice of Allowance by amending claim 1 to recite that "the solution has a pH from 6.0 to 8.2." (DTX-3.058). Applicants also requested withdrawal of one of the Examiner's grounds for rejection on the basis that "Pasternack and Lloyd do not disclose or suggest any pH" and that "Owoo describes a pH between 4.5 and 5.5 . . . below the range of 6.0 to 8.2." (DTX-3.058-59 & .072-73).

34. The '646 patent specification describes the normal pH for calcium gluconate, which is tied to the physiological pH of blood. (Bench Tr. at 68:24-69:9). That description includes the 6 to 8.2 range as one of the normal ranges used. (*Id.* at 74:2-13, 75:12-13, 76:3-7). The specification reads, "[n]ormally the pH will be between 5 and 8.5, more preferably between 6.0 and 8.2, and most preferably between 7 and 8." (JTX-1 at 2:31-33).

E. Person of Ordinary Skill in the Art

35. There is no dispute that the person of ordinary skill in the art with respect to the '646 patent, as of July 25, 2017, would have held an advanced degree (*e.g.*, PhD, RPh) in the field of pharmaceutical sciences, medicine, or a related discipline with at least two (2) or three (3) years of experience in his or her pertinent field, especially in injectable drug formulation, and/or a master's or undergraduate degree in a related field with several years of experience in his or her pertinent field, including in areas of formulating injectable dosage forms containing pharmaceutically active compounds. (Jury. Tr. at 610:22-6, 909:7-910:1). Such a person would have understood that the drug and product development processes require a multi-disciplinary approach; the skilled person would have drawn upon not only his or her skills, but also could have taken advantage of certain specialized skills of a team that may have included, for example, a pharmacist with experience in the compounding of drug products, or a physician with experience in the administration, dosing and efficacy of drugs for the relief of symptoms of hypocalcemia, to solve any given problem. (*Id.* at 611:6-16).

F. The Prosecution Of The '646 Patent

36. Kevin E. Weddington was the primary examiner at the U.S. Patent and Trademark Office ("PTO") during the prosecution of the '705 application. (*See* JTX-1 at 2; Bench Tr. at 2:22-24).

37. Mr. Kelly prosecuted the '646 patent. (*See* Bench Tr. at 12:19-13:3; Jury Tr. at 576:9-12). He is an experienced attorney in the field of patent prosecution, having practiced patent law for many years. (Bench Tr. at 13:9-25). Mr. Kelly worked with Mr. Pizza for many years before prosecuting the '646 patent. (*Id.*).

38. Neither Mr. Pizza nor Ms. Squeglia is an attorney or an expert in patent prosecution. (*Id*. at 11:21-12:12, 37:14-16, 48:4-10). Instead, they relied on Mr. Kelly's expertise in this area. (*Id.* at 11:4-12:8, 33:16-19).

39. Mr. Pizza did not collect or provide any documents to Mr. Kelly during the prosecution of the '646 patent family of applications. (*Id*. at 7:22-8:10).

40. Mr. Kelly acknowledged in his testimony that "Joseph Pizza had no knowledge of any references material to the prosecution of either the '646 or the '813 patent," and further doubted whether Mr. Pizza "had any knowledge of the [prior art] references" at all. (*Id.* at 70:19-71:2). Instead, Mr. Pizza relied on Ms. Squeglia to provide materials that Mr. Kelly needed for prosecution of the patent applications at issue. (*Id.* at 7:22-8:10).

41. Ms. Squeglia was responsible for coordinating the prosecution of the '646 patent with Mr. Kelly on behalf of HQ and Mr. Pizza. (*Id*. at 23:7-15). She is not and was not at the time of the relevant events, knowledgeable about the patent prosecution process. (*Id*. at 37:14-16, 48:4-10).

42. Mr. Pizza and Ms. Squeglia relied on Mr. Kelly to educate and inform them as to the information that he needed in connection with the prosecution. (*Id*. at 11:4-14, 41:20-24).

43. Mr. Pizza and Ms. Squeglia each testified that they did not withhold any documents or information asked for by Mr. Kelly. (*Id.* at 18:6-13; 53:23-54:5). That testimony was credible.

44. Mr. Kelly made the decision as to what references were disclosed to the PTO as part of the prosecution of the '646 patent. (*Id*. at 83:5-8).

45. Ms. Squeglia deferred to Mr. Kelly on the issue of what references were cited to the PTO. (*Id*. 36:25-37:16). She testified that, after she gave Mr. Kelly the references, she was not sure which ones were ultimately submitted to the PTO. (*Id.*).

46. Ms. Squeglia testified that she generally did not know what was material for the purposes of submissions to the PTO: "I don't know what becomes important and not important, I'm not a patent attorney. I have no idea." (*Id.*).

47. Ms. Squeglia also explained, with respect to specific references, "I wasn't aware I had to give any of this stuff to [Mr. Kelly]," and "I had no reason to believe that I had to give [Mr. Kelly] this information." (*Id.* at 35:5-6, 41:20-24).

48. Mr. Kelly testified that Ms. Squeglia was responsible for providing the scientific data and testing used in the '646 patent application. (*Id*. at 69:24-70:11; Jury Tr. at 578:19-22).

49. Ms. Squeglia provided Mr. Kelly with information about the prior art calcium gluconate vial products, including information with which Mr. Kelly could find the labels. (Bench Tr. at 49:14-50:12, 72:16-24). It was her understanding that the information about the vials was included in the patent at column 1, in the "Background of the Invention" section. (*Id.*).

50. Ms. Squeglia believed that the description of those vial products in the specification of the '646 patent was sufficient to make the Examiner aware of that prior art. (*Id.*).

51. Ms. Squeglia was not aware that there was any reason to provide FDA communications to the PTO. (*Id*. at 32:15-18).

52. Ms. Squeglia testified that she gave Mr. Kelly the 2009 APP label, or information sufficient to find the 2009 APP label, and that testimony was credible. (*Id*. at 36:6-37:19).

53. Mr. Kelly testified that he knew of the existence of the APP label during patent prosecution, and that testimony was credible. (*Id*. at 72:16-24). Mr. Kelly had no recollection of reviewing the APP label, or any other label or packaging for prior art calcium gluconate injection products. (*Id.* at 72:25-73:3).

54. Mr. Kelly testified to his belief that the disclosures that were made in the specification of the '646 patent were sufficient disclosures of the prior art vial product, and the pH of the prior art calcium gluconate products were sufficient to put the Examiner on notice of what the prior art taught in terms of the pH of calcium gluconate prior art. (*Id*. at 78:17-79:16). That testimony was credible.

55. Mr. Kelly testified that he understood that the pH claimed in the patent was the "physiological pH" and that, as a result, he believed that any person of skill in the art would have been aware of that pH range. (*Id*. at 73:23-76:7).

56. Mr. Kelly was aware that HQ was planning to submit an FDA application under Section 505(b)(2). (*Id.* at 71:8-72:15). He did not request that HQ provide him with the materials it filed with the FDA in support of its application to the PTO. (*Id*.).

57. Mr. Kelly testified that he did not believe the labels or HQ's communications with the FDA were material, and that Applicants therefore complied with their duty to submit all material statements to the PTO. (*Id*. at 68:11-23, 71:21-72:1, 74:14-25, 78:10-16 ("I don't see it being material.")). That testimony was credible regarding Mr. Kelly's subjective belief.

58. Mr. Kelly testified that he believed the information disclosed in the labels, including the pH, was already disclosed in the patent application, which – as originally filed – disclosed that calcium gluconate is "available as aqueous solutions of calcium gluconate in 10 mL glass vials and 100 mL rigid plastic bottles." (*Id*. at 78:10-79:16; JTX-1 at 1:32-35). Based on

that language, Mr. Kelly testified he believed "we disclosed" the Fresenius vial product: "we put it right in the first part of the patents so the Examiner would see it." (Bench Tr. at 78:17-79:16). That testimony was credible.

59. As of July 2017, the priority date of the '646 patent, Fresenius's vial was the only calcium gluconate vial product on the market. (*Id*. at 85:20-23).

60. A person of ordinary skill in the art would have understood that the disclosures in column 1 were describing the commercially available vial product, which at the time of patent prosecution would have been the Fresenius vial. (*Id*. at 79:6-16, 85:20-86:24).

61. Fresenius's expert, Dr. Rabinow, testified that a person of ordinary skill in the art would have been able to find the 2017 FK Label quickly, in as little as three minutes. (*Id.* at 86:14-24).

62. Prior to its 2017 plastic vial product, Fresenius' predecessor, APP, had for decades sold the same formulation of calcium gluconate in glass vials as a grandfathered product that did not require FDA approval. (*Id*. at 86:3-13).

G. Prior Art & Materiality

63. The '646 patent lists Pasternack, Owoo, and Lloyd as the references cited to the Examiner during prosecution. (JTX-1 at 2).

64. The 2017 FK Label is prior art to the '646 patent, lists a pH range of 6.0 to 8.2, and was publicly available before the July 2017 priority date of the '646 patent. (DTX-6.008; Jury Tr. at 611:21-612:7).

65. The 2009 APP Label was publicly available before the July 2017 priority date of the '646 patent. (DTX-197.007-10; D.I. 215, Ex. 1 ¶ 75).

66. The 2013 USP Monograph (PTX-26) was publicly available before the July 2017 priority date of the '646 patent. (Jury Tr. at 612:13-14).

67. The 2017 FK Label, 2009 APP Label, and 2013 USP Monograph, do not describe a terminally sterilized calcium gluconate bag product that was fully diluted and sterilized after it was placed in the bag. (*See id.* at 836:4-14; DTX-197.007-010).

68. The '646 Patent specification describes the normal pH for calcium gluconate, which is tied to the physiological pH of blood. (Bench Tr. 68:24-69:9). That description includes the 6 to 8.2 range as one of the normal ranges used. (JTX-1 at 2:31-33) ("Normally the pH will be between 5 and 8.5, more preferably between 6.0 and 8.2, and most preferably between 7 and 8.").

69. The '646 patent does not disclose the dilution instructions for the prior art vial products, the labels or package inserts for the prior APP or Fresenius calcium gluconate vial products, such as the 2009 APP or 2017 FK Labels, or the formulation of any calcium gluconate IV bags compounded from the prior art vial products. (*See* JTX-1 at 1:18-2:5; Bench Tr. at 36:1-37:1).

70. Ms. Squeglia and Mr. Pizza were both aware of the 2009 APP and 2017 FK Labels. (Bench Tr. at 25:12-14; DTX-75, 197). Each of those labels discloses that the Fresenius calcium gluconate vial product has a pH value of 6 to 8.2. (DTX-6.008, 197.007).

H. <u>The FDA Application</u>

71. HQ filed a 505(b)(2) NDA that relied on the safety and efficacy of Fresenius's previously approved calcium gluconate vial product as the RLD. (Jury Tr. at 323:9-325:5, 783:24-784:15). HQ submitted a Request for a Waiver from Bioequivalence Study to the FDA dated September 25, 2017, signed by Mr. Pizza, representing to the FDA that "[t]he proposed Calcium Gluconate Injection, 1 g/50 mL, 2 g/100 mL (20 mg/mL) drug product formulation (subject of this

NDA) contains the same active ingredients, same route of administration and indications as the drug product that is the subject of an approved full new drug application, also known as reference listed drug (RLD), Calcium Gluconate Injection, 100 mg/mL® of Fresenius Kabi USA, LLC, approved June, 15, 2017." (DTX-193; Jury Tr. at 325:6-326:5).

72. HQ's communications with the FDA describe the prior art vial products after dilution. (Bench Tr. at 28:15-21).

73. HQ's December 15, 2017 submission to the FDA was not submitted or disclosed to the PTO while the '646 patent application was pending between January 11, 2018 and November 20, 2018. (DTX-75.001-06; Bench Tr. at 32:8-18).

74. Ms. Squeglia did not recall telling Mr. Kelly about HQ's December 15, 2017 submission to the FDA and testified that she would not have known to submit the FDA filing to the PTO. (Bench Tr. at 32:3-23).

75. Mr. Kelly did not ask Ms. Squeglia or Mr. Pizza for HQ's submission to the FDA, because he did not believe it was relevant to the patent application. (*Id*. at 32:3-23, 71:21-72:6).

76. Although Mr. Kelly did not recall the labeling of the APP or Fresenius calcium gluconate vial product, he did vaguely recall "looking at drugs at FDA to see what was out there." (*Id.* at 37:2-19, 80:3-25).

77. Mr. Kelly was aware that HQ had filed (or was planning to file) an FDA application under Section 505(b)(2). (*Id*. at 71:8-72:15). He did not request that HQ provide him with the materials it filed with FDA in support of its application. (*Id.*). Mr. Kelly was not aware of the specific contents of those filings, including what statements were made to the FDA. (*Id.*).

78. Mr. Kelly testified that he did not believe the labels or HQ's communications with the FDA were material, and that testimony was credible with regard to Mr. Kelly's subjective belief. (*Id*. at 71:21-72:1, 78:10-16).

I. Dr. Dusci as Inventor

79. The InfoRLife team, led by Dr. Dusci, had extensive experience in pharmaceutical formulation and referenced the 2009 APP Label and 2013 USP Monograph during formulation of the claimed invention of the '646 patent, including the prior art calcium gluconate labels. (*See* Jury Tr. at 313:17-314:7; DTX-79.001, 195, 242).

80. Dr. Dusci provided no testimony in this case.

81. Ms. Squeglia sent Dr. Dusci a draft of the application that ultimately led to the issuance of the '646 patent. (DTX-188).

82. Mr. Pizza testified that, in his view, he alone should be the named inventor of the '646 patent. (Jury Tr. at 273:5-279:25, 283:25-287:2).

J. Specific Intent to Deceive

83. Mr. Pizza understood that he owed a duty of disclosure to the PTO during the prosecution of the '646 patent family of applications. (Bench Tr. at 7:6-21).

84. Ms. Squeglia understood that she owed duties of disclosure and candor to the PTO during the prosecution of the '646 family of applications. (*Id*. at 25:1-11). She also understood that she was required to provide material information to Mr. Kelly to comply with her duty of candor. (*Id*.).

85. Mr. Kelly understood that he had a duty to disclose information that was relevant and material to the claims being prosecuted to the PTO. (*Id*. at 67:21-68:3, 74:14-18).

86. Mr. Kelly understood that there was a duty of candor to the PTO associated with material statements received from or submitted to the FDA. (*Id*. at 68:15-23). Mr. Kelly testified that he believed Plaintiffs complied with that duty. (*Id*.).

87. Mr. Kelly understood that there was a duty to correct erroneous statements made to the PTO. (*Id*. at 75:1-4).

88. Mr. Kelly understood that the duty of candor does not end until issuance of the patent. (*Id*. at 76:8-11).

89. Mr. Kelly testified that he did not intend to deceive the PTO, and that testimony was credible. (*Id*. at 74:19-25).

90. Mr. Pizza testified that he did not intend to deceive the PTO, and that testimony was credible. (*Id.* at 18:6-13).

91. Ms. Squeglia testified that she did not intend to deceive the PTO, and that testimony was credible. (*Id.* at 54:2-5).

III. CONCLUSIONS OF LAW

A. Legal Standard for Inequitable Conduct

"Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). "Unlike validity defenses, which are claim specific, inequitable conduct regarding a single claim renders the entire patent unenforceable." *Regeneron Pharms., Inc. v. Merus N.V.*, 864 F.3d 1343, 1350 (Fed. Cir. 2017). "To prove inequitable conduct, a party must show that [(1)] the patentee withheld material information from the PTO," such as a prior art reference, "and [(2)] did so with the specific intent to deceive the PTO." *Luv n' Care, Ltd. v. Laurain*, 98 F.4th 1081, 1096-97 (Fed. Cir. 2024). "Withholding of material information and intent to deceive or

mislead must be established by clear and convincing evidence." *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1290 (Fed. Cir. 2012).

As to the first element, "the materiality required to establish inequitable conduct is but-for materiality." *Therasense*, 649 F.3d at 1291. "Prior art is but-for material if the PTO would have denied a claim had it known of the undisclosed prior art[, but] is not but-for material if it is merely cumulative." *Cal. Inst. of Tech. v. Broadcom Ltd.*, 25 F.4th 976, 991 (Fed. Cir. 2022) (citing *Regeneron*, 864 F.3d at 1350). "A reference is cumulative when it teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO." *Regeneron*, 864 F.3d at 1351 (internal quotation marks omitted).

The second element "the accused infringer must prove [is] that the patentee acted with the specific intent to deceive the PTO." *Therasense*, 649 F.3d at 1290. "[G]ross negligence or negligence under a 'should have known' standard does not satisfy this intent requirement." *Id.* "In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference." *Regeneron*, 864 F.3d at 1351 (quoting *Molins PLC v. Textron, Inc.,* 48 F.3d 1172, 1181 (Fed. Cir. 1995)). "Proving that the patentee knew of a reference, should have known of its materiality, and decided not to submit it to the USPTO does not prove specific intent to deceive." *GS Cleantech Corp. v. Adkins Energy LLC*, 951 F.3d 1310, 1324 (Fed. Cir. 2020) (alterations and citation omitted). Instead, "deceptive intent must be the single most reasonable inference based on the evidence." *Luv n' Care*, 98 F.4th at 1097. "Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Therasense*, 649 F.3d at 1290-91.

"Direct evidence of intent is not, however, required. A court may infer intent from circumstantial evidence." *Regeneron*, 864 F.3d at 1351. An inference of intent to deceive is

appropriate where the applicant engages in "a pattern of lack of candor," including where the applicant repeatedly makes factual representations "contrary to the true information he had in his possession." *Apotex Inc. v. UCB, Inc.*, 763 F.3d 1354, 1362 (Fed. Cir. 2014). Nevertheless, "the evidence must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances." *Therasense*, 649 F.3d at 1290-91 (internal quotation marks omitted).

B. Discussion

1. Specific Intent To Deceive The PTO

To prove specific intent for the purposes of an inequitable conduct claim, "the accused infringer must prove by clear and convincing evidence that the applicant [(1)] knew of the [omitted] reference, [(2)] knew that it was material, and [(3)] made a deliberate decision to withhold it." *Therasense*, 649 F.3d at 1290.

Here, Fresenius asserts four bases for finding that Plaintiffs acted with specific intent to deceive the PTO: (1) Plaintiffs should have known of the materiality of the 2017 FK Label, the 2009 APP Label, and the 2013 USP Monograph ("the Prior Art References"); (2) Plaintiffs lack a credible explanation as to why they did not disclose the Prior Art References to the PTO; (3) Plaintiffs made inconsistent representations to the PTO and FDA; and (4) Plaintiffs intentionally omitted Dr. Dusci as a named inventor. (D.I. 283 at 14-20). The Court evaluates these arguments within the specific intent rubric and finds that none of them prove by clear and convincing evidence that Plaintiffs acted with specific intent.[3]

[3] Because the Court finds that Plaintiffs have not proven specific intent by clear and convincing evidence, it need not entertain the materiality arguments. *See Therasense*, 649 F.3d at 1290 ("Intent and materiality are separate requirements. . . . a court must weigh the evidence of intent to deceive independent of its analysis of materiality."). Put another way, "even assuming the but-for materiality of the references, [Defendant] has not proven by clear and convincing evidence that [Plaintiffs] committed inequitable conduct before

a. Knowledge of Prior Art & Materiality

First, Fresenius says that Plaintiffs "should have known" of the materiality of the Prior Art References, and, thus, it is appropriate to draw an inference that they acted with specific intent to deceive. (D.I. 283 at 14-15). That, however, is not the law. Since *Therasense*, the seminal case on inequitable conduct issued more than a decade ago, Federal Circuit precedent is clear that "gross negligence or negligence under a 'should have known' standard does not satisfy th[e] intent requirement." 649 F.3d at 1290; *In re Rosuvastatin Calcium Pat. Litig.*, 703 F.3d 511, 522 (Fed. Cir. 2012) ("[N]egligence – even gross negligence – is insufficient to establish deceptive intent."). Instead, "clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference." *Regeneron*, 864 F.3d at 1351 (quoting *Molins*, 48 F.3d at 1181).

"Proving that the patentee knew of a reference, should have known of its materiality, and decided not to submit it to the USPTO does not prove specific intent to deceive." *Cleantech*, 951 F.3d at 1324. Put differently, "[i]ntent and materiality are separate requirements." *Therasense*, 649 F.3d at 1290. The contrary support upon which Fresenius relies predates *Therasense*. *See, e.g.*, *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997); *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1241 (Fed. Cir. 2008); *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1239 (Fed. Cir. 2003). It is, therefore, unpersuasive.

Turning next to the facts, the Court does not accept Fresenius' conclusion that "there can be no dispute that [Plaintiffs] knew the materiality of the [Prior Art] References." (D.I. 283 at 14-15). Trial testimony from Mr. Pizza, Ms. Squeglia, and Mr. Kelly shows the opposite.

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the PTO." *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 923 F. Supp. 2d 602, 688 (D. Del. 2013), *aff'd*, 752 F.3d 967 (Fed. Cir. 2014).

First, as to Mr. Pizza, it was established that he was minimally involved in the prosecution of the '646 patent, if at all. (FF ¶¶ 37-42). He is not a patent attorney. (*Id.* ¶ 38). He did not collect any documents for submission to Mr. Kelly or the PTO. (*Id.* ¶¶ 39-40). He did not withhold any documents or information from Mr. Kelly. (*Id.* ¶ 43). In fact, he was not asked for any. (*Id.* ¶ 75). Rather, Mr. Pizza relied on Ms. Squeglia to handle the internal side of the prosecution and Mr. Kelly to lead the process externally before the PTO. (*Id.* ¶¶ 40-42). Specifically with respect to his knowledge of relevant prior art references, credible trial testimony acknowledged that "Joseph Pizza had no knowledge of any references material to the prosecution of either the '646 or the '813 patent," and doubted whether he "had any knowledge of the references" at all. (*Id.* ¶ 40).

As for Ms. Squeglia, although she was assigned the task of coordinating the prosecution with Mr. Kelly, she, like Mr. Pizza, was unsophisticated with respect to patent prosecution. (*Id.* ¶¶ 38, 41-47). As the VP of Technical Affairs, her professional focus was on getting Plaintiffs' products developed, manufactured, and approved by the FDA. (*Id.* ¶ 7). For that reason, she deferred to Mr. Kelly as to what documents should be submitted to the PTO. (*Id.* ¶¶ 42-45). She testified credibly that she generally did not know what constitutes legal materiality: "I don't know what becomes important and not important, I'm not a patent attorney. I have no idea." (*Id.* ¶ 46). And as to the specific Prior Art References challenged by Fresenius, she explained, "I wasn't aware I had to give any of this stuff to [Mr. Kelly]," and "I had no reason to believe that I had to give [Mr. Kelly] this information." (*Id.* ¶ 47) ("I was not aware that . . . this should have been provided to [Mr. Kelly]."). That testimony rang true given Mr. Kelly's corroborating testimony that he was the one in charge of deciding which references would be submitted to the PTO. (*Id.* ¶ 44).

To that same end, Mr. Kelly stated that he disclosed all references he understood to be material to the prosecution in column 1 of the '646 patent. (*Id.* ¶¶ 54-58). Pasternak, Owoo, and Lloyd were additionally listed in the References Cited section. (*Id.* ¶ 63). And with respect to Fresenius' calcium gluconate vial – the lone such product on the market at the time – Mr. Kelly insisted: "we disclosed that . . . we put it right in the first part of the patents so the Examiner would see it." (*Id.* ¶ 58). The same is true for the claim elements; Mr. Kelly stated that the "physiological pH" range of between 6 and 8 was "disclosed in the specification as being normal." (*Id.* ¶¶ 34, 54-55, 68).

Moreover, Mr. Kelly further testified that he did not view the 2017 FK Label or FDA statements to be material, (*id.* ¶¶ 57-58), because "[t]he invention in the patents . . . was putting this [calcium gluconate formula] in the flexible bags." (Bench Tr. at 71:21-72:1, 78:10-16). He explained that Plaintiffs "acknowledged that vials of [calcium gluconate] were out there being used that were being diluted and ***our invention was getting away from these rigid containers and getting into the flexible – the flexible bags***, which is what the hospital wanted with the ready-to-use product that they didn't have to touch." (*Id.* at 79:10-16) (emphasis added). That testimony was supported by Dr. Rabinow's opinion that a skilled artisan could readily find the 2017 FK Label, given that it was the only vial product on the market at the time. (FF ¶¶ 59-61).

Fresenius counters that Mr. Pizza and Ms. Squeglia must have known the Prior Art References were material because Plaintiffs based the calcium gluconate formulation of the '646 patent on Fresenius' earlier vial product. (D.I. 283 at 14-15; FF ¶¶ 70-71). But again, this is the same circular "should have known" inference that is insufficient under the law and in tenson with the testimony elicited at trial. Thus, the Court finds that Fresenius has failed to prove by clear

and convincing evidence that Plaintiffs' agents knew of material prior art references that were withheld from the PTO.

b. Deliberate Decision to Deceive the PTO

Fresenius next contends that Plaintiffs have "no credible explanation" for the nondisclosure of the Prior Art References, and, therefore, the only inference to be drawn is that Plaintiffs made a deliberate decision to deceive the PTO. (D.I. 283 at 15). According to Fresenius, Mr. Pizza, Ms. Squeglia, and Mr. Kelly "engaged in an elaborate pattern of non-disclosure" to hide the ball from the PTO, while using the same information to secure FDA approval. (*Id.* at 16). And their trial testimony, which Fresenius paints as "excuses" that disclosure fell between the cracks of each individual's responsibility, "completely lacked credibility." (*Id.* at 6, 15). The Court addresses each argument in turn.

i. Plaintiffs' Explanation

At the outset, the Court notes that it is Fresenius' burden to clearly and convincingly prove specific intent to deceive, including that foul play is the "single most reasonable inference" that can be drawn from the evidence of Plaintiffs' conduct. *Freshub, Inc. v. Amazon.com, Inc.*, 93 F.4th 1244, 1252 (Fed. Cir. 2024); *Luv n' Care*, 98 F.4th at 1097. Fresenius tries to cut into that burden by citing a string of cases for the proposition that "the lack of any credible explanation for nondisclosure" of a reference may support an inference of deceptive intent. *McKesson Info. Sols., Inc. v. Bridge Med., Inc*., 487 F.3d 897, 919 (Fed. Cir. 2007); *see also Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd*., 394 F.3d 1348, 1354 (Fed. Cir. 2005); *Monsanto*, 514 F.3d at 1241; *Critikon*, 120 F.3d at 1257.

But, as before, each of those cases was decided before *Therasense*,[4] which expressly states that "[t]he absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive." 649 F.3d at 1291. To the contrary, "[b]ecause the party alleging inequitable conduct bears the burden of proof, the patentee need not offer any good faith explanation ***unless the accused infringer first proves a threshold level of intent to deceive*** by clear and convincing evidence." *Id.* (cleaned up, emphasis added); *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, No. 10-805 (RGA), 2012 WL 2951965, at *2 (D. Del. July 19, 2012). Fresenius has not made that threshold showing here.

Setting the law aside, there are also several factual flaws in Fresenius' theory. For one, Ms. Squeglia did point Mr. Kelly to relevant prior art during the prosecution of the '646 patent. (FF ¶¶ 49-52). She "told [him] about the calcium gluconate vial product" that was on the market at the time – Fresenius' product – and gave him information sufficient to research the labels himself. (*Id.*). Thus, rather than withholding, that testimony demonstrates that Ms. Squeglia disclosed relevant references to Mr. Kelly.

Fresenius answers that, if it was not Ms. Squeglia who perpetrated the wrongful withholding, it was Mr. Kelly. But the obstacle there is that Mr. Kelly did not believe the references to be material. (FF ¶ 57) ("I don't see it being material."). That is an alternative credible explanation for why he did not submit them to the PTO, and "when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." *Therasense*, 649 F.3d at 1290-91; *see also Bristol-Myers Squibb*, 923 F. Supp. 2d at 688-89. Fresenius did not adduce any documentary or testimonial evidence to directly undermine that position.

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[4] And, in any event, the rulings in those cases rest in part on findings of strong affirmative evidence – absent here – pointing to misconduct. *See, e.g.*, *McKesson*, 487 F.3d at 919 ("[T]he overwhelming circumstantial evidence, coupled with the lack of any credible explanation for nondisclosure of [the prior art], supports the finding of deceptive intent.").

And even if it did, that would still not be enough, because "[k]nowledge of the reference and knowledge of materiality alone are insufficient after *Therasense* to show an intent to deceive." *1st Media, LLC v. Elec. Arts, Inc.*, 694 F.3d 1367, 1374-75 (Fed. Cir. 2012). Indeed, noticeably missing from the trial evidence was a "deliberate decision" – anything showing that Mr. Kelly affirmatively withheld a reference, or that Mr. Pizza or Ms. Squeglia affirmatively refused to provide Mr. Kelly with a requested reference. (*Cf.* FF ¶ 43). Absent that, Fresenius' circumstantial case does not rise to meet its clear and convincing burden.

ii. Plaintiffs' Statements to the PTO and FDA

Fresenius additionally asserts that the Court should draw a negative inference of deception from the fact that Plaintiffs made different submissions and statements to the PTO and FDA. (D.I. 283 at 17). At the outset, it bears mention that obtaining "[a]pproval of a new drug by [the] FDA . . . is a more demanding standard than that involved [for] the patent[]-in-suit." *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1372 (Fed. Cir. 2017), *aff'd*, 586 U.S. 123 (2019). An FDA applicant would therefore be expected to buttress its submission with more support than it otherwise would in a corresponding patent application. Accordingly, "the mere fact that Plaintiff[s] [as] the applicants submitted different applications to the FDA and to the PTO does not, alone, make plausible any inference of misconduct." *Jazz Pharms. Ireland Ltd. v. Lupin Inc.*, No. 21-14271 (SRC), 2025 WL 517856, at *7 (D.N.J. Feb. 18, 2025) ("[P]atent law does not apply the demanding standard that the FDA applies during the new drug approval process.").

Fresenius says there is more; the same individuals "were involved in both the FDA and PTO submissions." (D.I. 283 at 17) (quoting *Bruno*, 394 F.3d at 1354). Ignoring, for the moment, that assertion once again rests on outdated pre-*Therasense* precedent, it is not quite accurate.

Ms. Squeglia oversaw the FDA submission, while Mr. Kelly led the PTO application. (FF ¶¶ 7, 37-38, 74-75). And Mr. Pizza was hardly involved in either. (*Id.* ¶ 38-40).

In any case, Fresenius retorts, Plaintiffs made an "about face" in their strategy by representing to the PTO that their product was novel but then telling the FDA that it was chemically bioequivalent to Fresenius' vial. (D.I. 283 at 18). The Court does not find those positions to be inconsistent. Mr. Kelly testified that he did not either. (FF ¶ 57). Plaintiffs had other rationales for the novelty of their patented product, such as the terminal sterilization, the ready-to-use free-flex bag presentation, or the extended 24-month shelf life. (*See, e.g.*, *id.* ¶¶ 20-22; Bench Tr. at 71:21-72:1, 78:10-16, 79:10-16). Any one or more of those provides a plausible rationalization for not focusing on the bioequivalence of the compound's formulation before the PTO.[5] *See Energy Heating, LLC v. Heat On-The-Fly, LLC*, 889 F.3d 1291, 1302 (Fed. Cir. 2018). By contrast, the chemical composition would have been far more important to the FDA's new drug analysis. *See Helsinn*, 855 F.3d at 1372.

In the end, it may well have been "better practice for [Plaintiffs] to have disclosed the FDA [application] to the [PTO] Examiner." *The Rsch. Found. of State Univ. of N.Y. v. Mylan Pharms. Inc.*, 723 F. Supp. 2d 638, 657 (D. Del. 2010) ("Patent applicants are expected to err on the side of disclosure."). Even so, Plaintiffs' "knowledge and non-disclosure . . . do not themselves constitute inequitable conduct rendering [t]his patent[] unenforceable." *Id.*

[5] Moreover, as Mr. Kelly, Mr. Pizza, and Ms. Squeglia all testified, they did not believe the FDA statements to be material to or a requisite for the PTO submission. (Bench Tr. at 71:21-24, 72:2-15). Fresenius did not enter any documentary evidence or elicit any testimony at trial to rebut that good faith belief. *See Freshub*, 93 F.4th at 1253 (upholding finding of no inequitable conduct where "the record [presented by the infringer] was thin").

c. Plaintiffs' Intent as to Inventorship

Finally, Fresenius claims that Plaintiffs intentionally sought to deceive the PTO by purposefully omitting Dr. Dusci as a named inventor on the '646 patent. (D.I. 283 at 19-20). This is part and parcel of Fresenius' broader hypothesis that Plaintiffs "engaged in a deceptive scheme to deprive the Examiner of critical, prior art calcium gluconate details by: (i) withholding material information from the PTO; and (ii) intentionally omitting Dr. Dusci as a named inventor to avoid disclosing his extensive knowledge of the prior art." (D.I. 301 at 9).

Plaintiffs contend that Fresenius waived this argument by failing to properly allege it in its Answer, (D.I. 297 at 11 & n.1; *cf.* D.I. 26 ¶¶ 197-225), since "[i]nequitable conduct . . . must be pled with particularity under Rule 9(b)." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009) (internal quotation marks omitted); *In re BP Lubricants USA Inc.*, 637 F.3d 1307, 1311 (Fed. Cir. 2011). Maybe it did. But Fresenius' argument is laid low by a more fundamental problem: the evidence does not support such a suggestion.

Yes, Fresenius points to three emails that it says highlight Plaintiffs' attempt to keep Dr. Dusci off the '646 patent. (*See* DTX-77.012, 175, 176). Setting aside that those exchanges took place at the beginning of the project – three years before the application was submitted to the PTO – they are principally about the *business* relationship between Plaintiffs and InfoRLife, not the scientific one. The correspondence discusses "ownership" of the product, whose "property" it will be, and the contours of a potential "partnership," including "expense sharing," a "profit split," and "the right of first refusal" in the event of a sale. (DTX-175, 176).

The strongest inference that can be drawn from those negotiations is that Plaintiffs tried to reserve the lion's share of the project's spoils for themselves, at InfoRLife's expense, not the circuitous conclusion that they wanted to trick Dr. Dusci so that they could in turn obscure his

knowledge of prior art from the PTO. *See Freshub*, 93 F.4th at 1252-53. Indeed, the Court has already found that Fresenius failed to prove that Plaintiffs intentionally withheld material prior art references from the PTO.

Thus, Fresenius' attenuated theory is a bridge too far from the "single most reasonable inference from the record," and the Court finds that Plaintiffs did not improperly hide Dr. Dusci's contributions as part of any inequitable campaign. *Id*. ("[Infringer's] arguments for drawing the necessary adverse inferences leave gaps.").

IV. CONCLUSION

The Court concludes, after considering the entire record and applicable law, that Fresenius has not proved by clear and convincing evidence that Plaintiffs HQ and WGCC engaged in inequitable conduct during the prosecution of the '646 patent. An appropriate order will be entered.